REMARKS

I. Introduction

The present amendment does not amend, add, or cancel any claims. Accordingly, claims 1-16 remain pending in the application. Claims 1 and 13 are independent.

II. Office Action Summary

In the Office Action of January 3, 2011, the Specification was objected to under 37 CFR §1.77(b). Claims 1, 2, and 8-16 were rejected under 35 USC §102(e) as being anticipated by U.S. Patent No. 6,611,698 issued to Yamashita et al. ("Yamashita"). Claims 3-7 were rejected under 35 USC §103(a) as being obvious over Yamashita in view of U.S. Patent No, 6,374,128 issued to Toida et al. ("Toida"). These rejections are respectfully traversed.

III. Objection to the Specification

The Specification was objected to under 37 CFR §1.77(b) as failing to provide the proper order for various sections of the application. Regarding this objection, the Office Action indicates that 37 CFR §1.77(b) provides guidelines for arranging different sections of the application, and suggests that these guidelines be used by the Applicant. The Office Action further alleges that any section heading which does not contain test should include the phrase "Not Applicable".

At the outset, Applicants note that the section identified in the Office Action merely provides "guidelines" that are suggested to be used by an Applicant. There is no specific statutory requirement that every section identified in the Office Action , or 37 CFR §1.77(b), must be incorporated in the Specification. Furthermore, the Office Action's assertion that the phrase "Not Applicable" should follow any section heading

that does not contain any text appears to be inaccurate. There is nothing in the cited regulation which indicates that such text should be incorporated in any section heading which does not contain any text.

In any event, Applicants have made various amendments to the Specification in order to provide headings which conform to those suggested in 37 CFR §1.77(b). Withdrawal of this objection is therefore respectfully requested.

IV. Rejection under 35 USC §102

Claims 1, 2, and 8-16 were rejected under 35 USC §102(e) as being anticipated by Yamashita. Regarding this rejection, the Office Action indicates that Yamashita discloses an optical measurement apparatus for living body that comprises a measurement channel including an irradiation use optical fiber that is set at an irradiation position on a body surface and irradiates an inspection light having a predetermined frequency. The Office Action further indicates that Yamashita discloses a light receiving use optical fiber which is set at a light receiving portion adjacent to the irradiation use optical fiber and receives the inspection light irradiated from the irradiation use optical fiber and penetrated through inside the subject. Yamashita is further indicated as disclosing a light detection unit, and a signal calculation and processing unit that includes a hemoglobin signal calculating unit which calculates a hemoglobin signal representing a hemoglobin concentration inside the subject. An optical fiber setting adequacy evaluation unit is also provided to evaluate the adequacy of setting on the body surface in the inspection area of the irradiation use optical fiber or the receiving use optical fiber. The Office Action additionally indicates that the signal calculation and processing unit includes a pulse wave calculation unit which calculates the intensity of a pulse wave component due

to heart beats of the subject contained in the hemoglobin signal, and that the optical fiber setting adequacy evaluation unit evaluates the adequacy of the setting on the body surface of the subject of the irradiation use optical fiber or the light receiving use optical fiber based on the intensity of the pulse wave component calculated by the pulse wave calculation unit. Applicants respectfully disagree.

Independent claim 1 defines an optical measurement apparatus for a living body that comprises:

> a measurement channel including an irradiation use optical fiber which is set at an irradiation position on a body surface in an inspection area of a subject and irradiates an inspection light having a predetermined frequency of from visible to near infrared range and a light receiving use optical fiber which is set at a light receiving portion adjacent the irradiation use optical fiber on the body surface in the inspection area and receives the inspection light irradiated from the adjacent irradiation use optical fiber and penetrated through inside the subject;
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> a light detection unit which detects the amount of inspection light received by the light receiving use optical fiber in an electrical signal; and
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> a signal calculation and processing unit including a hemoglobin signal calculating unit which calculates a hemoglobin signal representing a hemoglobin concentration inside the subject through which the inspection light has penetrated based on the electrical signal detected by the light detection unit and an optical fiber setting adequacy evaluation unit which evaluates adequacy of setting on the body surface in the inspection area of the irradiation use optical fiber or the light receiving use optical fiber both of which constitute the measurement channel, characterized in that
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> the signal calculation and processing unit further includes a pulse wave calculation unit which calculates an intensity of a pulse wave component due to heartbeats of the subject contained in the hemoglobin signal calculated by the hemoglobin signal calculation unit, and the optical fiber setting adequacy evaluation unit evaluates adequacy of setting on the body surface of the subject of the irradiation use optical fiber or the light receiving use optical fiber based on the intensity of the pulse wave component calculated by the pulse wave calculation unit.

The optical measurement apparatus of independent claim 1 includes a measurement channel, a light detection unit, and a signal calculation and processing unit. The measurement channel includes an irradiation use optical fiber that is set at an irradiation position on a body surface in an inspection area of a subject in order to irradiate an inspection light having a predetermined frequency ranging from visible to near infrared. The measurement channel also includes a light receiving use optical fiber which is set at a light receiving portion that is adjacent to the irradiation use optical fiber on the body surface in the inspection area in order to receive the inspection light irradiated from the irradiation use optical fiber and penetrated through inside the subject. The light detection unit detects the amount of inspection light received by the light receiving use optical fiber in the form of an electrical signal. The signal calculation and processing unit includes a hemoglobin signal calculating unit which calculates a hemoglobin signal representative of the hemoglobin concentration inside the subject based on the electrical signal detected by the light detection unit. The signal calculation and processing means also includes an optical fiber setting adequacy evaluation unit which evaluates the adequacy of setting the irradiation use optical fiber or the light receiving use optical use optical fiber on the body surface in the inspection area.

The irradiation use optical fiber and the light receiving use optical fiber also constitute the measurement channel. According to independent claim 1, the signal calculation and processing unit also includes a pulse wave calculation unit that calculates the intensity of a pulse wave component resulting from heart beats of the subject contained in the hemoglobin signal calculated by the hemoglobin signal calculation unit. Additionally, the optical fiber setting adequacy evaluation unit evaluates the adequacy of the irradiation use optical fiber or the light receiving use

optical fiber set on the body surface of the subject based on the intensity of the pulse wave component calculated by the pulse wave calculation unit.

As discussed in the Specification, oxy-Hb values due to hemoglobin oxidation of respective measurement channels for every measurement are determined from the measurement result of the optical measurement for living body. After extracting from the measurement result signal components in the frequency band which are presumed as containing the pulse wave components due the heartbeats, a frequency analysis is performed and the signal intensity P(f) for the respective frequency components f is calculated. A frequency having the maximum signal intensity among the signal components in the frequency band which are presumed as containing the pulse wave components due the heartbeats is detected as a center frequency fo from the result of performing the frequency analysis. See paragraphs [0037] and [0038]. A threshold value is then set, and the setting of the optical fibers is determined to be adequate or inadequate based on whether the fourth order statistic is determined to be above or below the threshold value. The Specification also indicates that the fourth order statistic depends on the amount of measurement light being used. Thus, it becomes possible to correctly judge whether or not the optical fibers have been adequately set on the body surface of the subject.

The Office Action alleges that Yamashita discloses all of the features recited in independent claim 1. Applicants' review of this reference, however, suggests otherwise. Yamashita discloses an optical measuring instrument for multi-channel simultaneous measurement wherein the intensity of light emitted from a light source is modulated at different frequencies, and the light is applied to multiple positions of a test object. The light is detected from the test object, converted into electrical signals by a photodiode, and modulation signals are detected by a lock-in amplifier

module. The signals are then processed by a processing unit in order to obtain information on the test subject interior. A preparatory measurement step is performed wherein light is sequentially applied from a light source, and the signal level of the detection light is measured for each light applied position. A control unit is used to control the light intensity and detection signal level in order to ensure that the difference in detection light levels is kept within a specified range.

Contrary to the assertions made in the Office Action, Yamashita does not disclose all of the features recited in independent claim 1. In particular, Applicants note that Yamashita merely discloses that the lock-in amplifier module (12) contains a total of 24 lock-in amplifiers (13-1 to 13-24) corresponding to each of the channels. The analog output signal from each lock-in amplifier characterizes the test subject (9), and is converted into a digital signal by an A/D converter (17). The measured signals are recorded by a recording unit (18), and processed to calculate changes in oxygenated hemoglobin concentration, or other parameters, based on the amount of detection light of two wavelengths for each measurement position. See column 8, line 56 to column 9, line 10. Yamashita further indicates that if a stray light level in the photodiodes exceeds a specified range, then the light detection position corresponding to such a photodiode is displayed on the display unit. The operator is then prompted to review the illumination level in the measurement chamber and installation of the optical fiber. This allows the operator to select a review mode to go back and reset the optical outputs from all the semiconductor lasers to zero, and perform a calculation assuming that the DC output from each photodiode is on the stray light level.

Yamashita appears to disclose a system that is similar to conventional systems. As discussed in the Background section of the Specification, an evaluation

and judgment can be performed to determine whether the setting of respective pairs of adjacent optical fibers each constituting a measurement channel of a probe device which is attached on a body surface of an inspection area of a subject is adequate or not by performing a gain adjustment for the respective measurement channels. If the gain adjustment fails for a given measurement channel, then the setting of the optical fibers is evaluated and judged as inadequate. The optical fibers are then reset for the respective concerned channels. Yamashita never discloses or suggests an optical fiber setting adequacy evaluation unit as recited in independent claim 1. Specifically, there is no disclosure for features recited in independent claim 1, such as:

> the signal calculation and processing unit further includes a pulse wave calculation unit which calculates an intensity of a pulse wave component due to heartbeats of the subject contained in the hemoglobin signal calculated by the hemoglobin signal calculation unit, and the optical fiber setting adequacy evaluation unit evaluates adequacy of setting on the body surface of the subject of the irradiation use optical fiber or the light receiving use optical fiber based on the intensity of the pulse wave component calculated by the pulse wave calculation unit.

It is therefore respectfully submitted that independent claim 1 is allowable over the art of record.

Claims 2-12 depend from independent claim 1, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 1. In addition, these claims each introduce novel elements that independent render them patentable over the art of record.

Independent claim 13 defines a method of optical measurement for a living body. The method of independent claim 13 recites various steps which correspond to functions performed by some of the elements of independent claim 1. In

particular, independent claim 13 requires a step of evaluating the setting adequacy on the body surface in the inspection area of the irradiation use optical fiber or the light receiving use optical fiber. Furthermore, this step includes a step of calculating the intensity of the pulse wave component due to heartbeats of the subject contained in the hemoglobin signal which is previously calculated. The setting adequacy of the irradiation use optical fiber or the light receiving use optical fiber is evaluated with respect to the body surface based on the calculated intensity of the pulse wave component. As previously discussed, Yamashita fails to provide any disclosure or suggestion for such features.

It is therefore respectfully submitted that independent claim 13 is allowable over the art of record.

Claims 14-16 depend from independent claim 13, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 13. In addition, these claims each introduce novel elements that independently render them patentable over the art of record.

V. Conclusion

For the reasons stated above, it is respectfully submitted that all of the pending claims are now in condition for allowance. Therefore, the issuance of a Notice of Allowance is believed in order, and courteously solicited.

If the Examiner believes that there are any matters which can be resolved by way of either a personal or telephone interview, the Examiner is invited to contact Applicants' undersigned attorney at the number indicated below.

AUTHORIZATION

Applicants request any shortage or excess in fees in connection with the filing of this paper, including extension of time fees, and for which no other form of payment is offered, be charged or credited to Deposit Account No. 01-2135 (Case: 529.46174X00).

Respectfully submitted,
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